

REMARKS/ARGUMENTS

Claims 1-4 and 13-35 remain in this application. Claims 1, 13-18, 23, 24, and 31 have been amended without prejudice, claims 8, 9, 11, and 12 have been cancelled without prejudice, and new claims 32-35 have been added. Applicants reserve the right to pursue such amended and cancelled subject matter in subsequent continuation applications. Support for the amendments to claims 1 and 26 can be found throughout the specification and claims (e.g., original claims 8 and 9). Accordingly, no issues of new matter are believed to be raised by the above amendments to the claims.

Rejection Under 35 USC 102

Claims 1-3, 19, 23, and 24 remained rejected under 35 USC 102 as being anticipated by US Patent No. 6,126,969 (the ‘969 Patent). See Pages 2-3 of the Office Action. According to the Office Action,

“the ‘969 patent teaches a dosage for comprising an immediate release portion and an extended releasing portion (abstract). The dosage form comprises sweeteners and other excipients . . . The extended release portion comprises coated core particles where the coating comprises and enteric polymer. The active agents include various well-known drugs including acetaminophen.”

See Page 2 of the Office Action.

As discussed above, independent claim 1 (from which claims 2,3, 19, 23, and 24 depend) has been amended to now recite wherein

“coating is comprised of a controlled release composition comprising an enteric polymer and an insoluble film forming polymer wherein the weight ratio of the insoluble film forming polymer and the enteric polymer is from about 80:20 to about 99:1”

Further, such a coating that comprises the recited ratio of both an enteric polymer and an insoluble film forming polymer is not suggested by Shah et al. Shah et al. actually teaches away from coating with enteric coating. As recited in the abstract of Shah et al, the particles of Shah et al. “provides controlled release which is independent of certain variable physiological factors

such as pH.” Thus, one of ordinary skill in the art would not look to Shah et al. to design the dosage form containing the coating recited in independent claim 1, as such coating contains an enteric polymer, which is a pH dependent polymer.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

Rejections Under 35 USC 103

Claims 1-4, 8,9, and 11-31 remain rejected under 35 USC 103(a) as being unpatentable over the ‘969 Patent in view of US Patent No. 5,637,320 (the ‘320 Patent). See Pages 3-5 of the Office Action. According to the Office Action,

“The ‘969 Patent discloses a dosage form comprising both an immediate release and an extended release portion. The extended release portion comprises a coating of enteric polymers, and is suggestive of a combination of polymers, but is silent to the specific polymer combinations and ratios of the instant claims. These combinations and ratios however are well within the level of skill in the art to obtain given the suggestion of the art, as shown in the ‘320 patent.”

See Page 3 of the Office Action.

As discussed above, independent claim 1 (from which claims 2-4, 13-25, and 29 depend), independent claim 26 (from which claims 28 and 30 depend), and independent claim 31 has been amended to now recite wherein the

“coating is comprised of a controlled release composition comprising an enteric polymer and an insoluble film forming polymer wherein the weight ratio of the insoluble film forming polymer and the enteric polymer is from about 80:20 to about 99:1.”

As discussed above, Shah et al. fails to disclose, or suggest, such a pharmaceutical dosage forms comprising such particles or methods as recited in the pending claims. The ‘320 Patent similarly fails to disclose or suggest such pharmaceutical dosage forms or methods.

Accordingly, Applicants assert that the presently claimed invention would not have been obvious to a person of ordinary skill in the art at the time of the claims invention was made in light of these references. Thus, Applicants respectfully request that this rejection under 35 USC 103(a) be withdrawn.

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Conclusion

For the foregoing reasons, the present application is in condition for allowance. Accordingly, favorable reconsideration of the amended claims in light of the above remarks and an early Notice of Allowance are courteously solicited. If the Examiner has any comments or suggestions that could place this application in even better form, the Examiner is requested to telephone the undersigned Attorney at the below-listed number.

If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 10-0750/MCP5015/WEM.

Respectfully submitted,

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